

Appl. No. 09/361,542  
Atty. Docket No. 7247M  
Amdt. dated December 13, 2006  
Reply to Office Action of June 16, 2006  
Customer No. 27752

## REMARKS

### Claim Status

Upon entry of the amendments herein, Claims 36, 38, 41-43, 46 and 48 will be pending in the present application. No additional claims fee is believed to be due.

Claim 44 has been canceled. Claims 36 and 43 have been amended. Support for the amendments is found at page 8, lines 30-32 and Claim 44 respectively for the percentages of silicon dioxide, and at page 6, lines 19-33 for the clarification with respect to the muco-retentiveness of the composition.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

### Rejection Under 35 USC §103(a) Over Beaurline et al. US 5,112,604

Claims 36, 38, 41-44, 46 and 48 are rejected under 35 USC §103(a) Over Beaurline et al. US 5,112,604 (hereinafter "Beaurline").

The Examiner asserts that Beaurline discloses oral, aqueous suspension formulations having a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water and other components. The Examiner asserts that, absent some unexpected advantage, the Applicant's claimed water ranges would be obvious because Beaurline uses "simple syrup" which contains water. In addition, although Beaurline only discloses up to 2% silicon dioxide, and not the claimed percentages of Claims 38 and 44, the Examiner asserts that it would be obvious to optimize the percent of silicon dioxide and thus meet the claimed percentages, in part because the Applicant uses the term "about".

The Applicant respectfully traverses the rejections. The Examiner has not met the burden of establishing a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references

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themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

Regardless of the amount of water that may or may not be present in Beaurline's "simple syrup" the present invention as a whole is not taught or suggested by Beaurline as discussed below.

The Examiner is correct that Beaurline does not disclose the Applicant's claimed ranges of silicon dioxide. Claim 44 has been canceled, thus obviating the rejection with respect to that claim. With respect to Claims 36, 38, and 41-43, 46, and 48, the Applicant's use of particular amounts of silicon dioxide assists in achieving the particular muco-retentive properties of the Applicant's invention. Beaurline teaches no more than 2% silicon dioxide, and particularly teaches levels much lower than 2%. Beaurline is only interested in maintaining the active in suspension for prolonging storage and promoting uniform dosing. Therefore, Beaurline does not provide any teaching, suggestion, motivation, desirability or expectation of success for using the amounts of silicon dioxide of the present invention, and therefore does not teach or suggest all of the claim limitations.

Furthermore, the Claims recite a "muco-retentive" composition, and clarify that said oral, muco-retentive, aqueous liquid, pharmaceutical composition forms a gel-like mixture upon contact with a mucosal surface. See page 8, lines 24-28 wherein the Applicant explains that the particulate component (including silicon dioxide) and its amount are chosen to provide the muco-adhesive benefit. See again page 6, lines 19 - 33 wherein the muco-retention is also discussed. See in addition, page 4, line 28 through page 5, line 2 wherein the muco-retentive properties of the present composition are described with respect to the colloidal particles (including silicon dioxide).

Beaurline teaches nothing with respect to muco-retentive compositions or muco-retentive properties, or any reason to make or desire such compositions or

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properties. Thus, one of skill in the art would not have been led by Beaurline to use the amounts of silicon dioxide used in the present invention.

Furthermore, regardless of the use of the term "about", the presently claimed ranges are outside of those disclosed by Beaurline, and as explained above, Beaurline teaches nothing with respect to muco-retentive compositions, or any need or desire to form such compositions. Therefore, the Applicant's use of the term "about" would not equate to simply "optimizing" the silicon dioxide amounts of Beaurline as the Examiner asserts. In addition, there is an unexpected, and un-taught, advantage of the present invention - that of muco-retentiveness which Beaurline does not even contemplate.

Therefore, because Beaurline does not teach or suggest all of the claim limitations, and does not teach or suggest, either implicitly or explicitly, any motivation or expectation of success for creating the compositions and methods of the present invention, the rejections have been overcome and the Applicant respectfully requests that the rejections be withdrawn.

Rejection Under 35 USC §112, 2<sup>nd</sup> Paragraph

Claims 36, 38, 41-44, 46 and 48 are rejected under 35 USC §112, 2<sup>nd</sup> paragraph because the Examiner asserts that the phrase "less than about" is indefinite because no specific lower limit has been given for the particle size.

The Applicant respectfully traverses the rejection. As noted, Claim 44 has been canceled, thus obviating the rejection with respect to that claim. With respect to particle size, the Examiner himself points out that colloidal particles are known to have a general size range. For clarification, as requested by the Examiner, see page 4, lines 28 - 35, wherein size range is discussed and context for the use of the term "about" is provided. Particularly, at page 4, lines 33 - 35 it is discussed that the particles of the invention are of colloidal size - such size described as being about 1 nm to about 10 microns. Thus, there is context and definition for the use of the phrase "less than about" with respect to colloidal sized particles when the Claims recite a mean particle size of less than about 1 micron. Therefore, the phrase "less than about" not indefinite with respect to particle

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size, and the rejections have been overcome. The Applicant therefore requests withdrawal of the rejections.

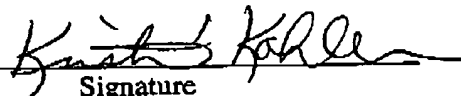
Conclusion

In light of the above remarks and amendments, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied documents. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of all pending Claims is respectfully requested.

Respectfully submitted,

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